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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,280	11/20/2003	Arlindo L. Castelhano	60390-IA/JPW/GJG/JBC	1457

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EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,280	CASTELHANO ET AL.	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *55-59* is/are allowed.

6)☒ Claim(s) *60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, see paper, filed 10/22/07, with respect to the rejection(s) of claim(s) 42-50 under 35 USC 112 1st paragraph and claims 55,57-60 under obviousness type double patenting have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is recited below.

I. Claim Rejection under 35 U.S.C. 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42-50 are no longer rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a subject afflicted with a disease associated with an A1 adenosine receptor via inhibiting the activity of the A1 adenosine receptor, does not reasonably provide enablement for treating specific diseases listed in claim 42. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make / use the invention commensurate in scope with these claims. The asserted utility is not believable on its face. It is not known how a method wherein a compound is claimed can be administered to treat all specifically named diseases in claim 42. The state of the

art is what prior art knows about the invention. There is no known art wherein a certain compound is administered to successfully treat all the specifically named disease. The level of ordinary skill in the art is high but only in the art of treating a specific disease with a specific compound or treating a group of related diseases with a specific compound. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by the applicant. In the instant invention the predictability is very low and consequently, the need for the higher levels of direction and guidance by the applicant. However, the amount of direction and guidance provided by the applicant is limited to treating a disease associated with an A1 adenosine receptor via inhibiting the activity of the A1 adenosine receptor. There is no evidence in the specification that establishes correlation between the experiment and the claimed utility (scope of diseases in claim 42). The quantity of experimentation required to use the method as claimed in the instant invention, based on applicant's disclosure would be undue because, one of ordinary skill in the art would have to perform a significant numbers of experiments.

Response to Applicants' argument

Claims 42-50 are cancelled. For this reason the 112 1st paragraph rejection is withdrawn.

III. Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 55,57-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 8 of copending Application No. 10/497,451. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions embrace the same compound. USAN '451 discloses the instant compound employed in the present application. USAN '451 does not teach the compound being in a composition or package as claimed in present application. However, in the making of the compound, it would have been obvious to use a solvent (carrier). Also, in the making of the compound, it would have been obvious to place the final product in some sought of container (package).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Applicants' argument

A terminal disclaimer has been provided to overcome the above double rejection over 10/497,451. For this reason the Obviousness type Double Patenting rejection is withdrawn.

New Rejection

I. Claim Rejection under 35 U.S.C. 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 60 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a subject afflicted with allergic inflammation, asthma, renal failure associated with an A1 adenosine receptor via inhibiting the activity of the A1 adenosine receptor according the state of the art. See Nyce & Metzger, DNA antisense Therapy for Asthma in an Animal Model, Nature, 1977, 385, 721-725. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make / use the invention commensurate in scope with these claims were "a disease" (any disease or all diseases) associate with the activity of A1 adenosine receptor. It is not known how a method wherein a compound is claimed can be administered to treat all diseases as

recited in claim 60. The state of the art is what prior art knows about the invention. There is no known art wherein a certain compound is administered to successfully treat all diseases. The level of ordinary skill in the art is high but only in the art of treating a specific diseases with a specific compound or treating a group of related diseases with a specific compound. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by the applicant. In the instant invention the predictability is very low and consequently, the need for the higher levels of direction and guidance by the applicant. However, the amount of direction and guidance provided by the applicant is limited to treating a disease associated with an A1 adenosine receptor via inhibiting the activity of the A1 adenosine receptor. There is no evidence in the specification that establishes correlation between the experiment and the claimed utility (scope of diseases in claim 60). The quantity of experimentation required to use the method as claimed in the instant invention, based on applicant's disclosure would be undue because, one of ordinary skill in the art would have to perform a significant numbers of experiments.

Allowable Subject Matter

Claims 55-59 are allowable. The prior art does not teach or suggest a pharmaceutical composition or package comprising the instant compound.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alton Pryor
Primary Examiner
AU 1616